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Final

VICH STRATEGY
Phase II 2006-2010

Introduction What is VICH?

VICH is a program of collaboration primarily between the regulatory authorities and the animal health industry, of the EU, Japan and the USA as member countries that aims to harmonise technical requirements for registration of Veterinary Medicinal Products and post-marketing surveillance. Australia, New Zealand and Canada are also VICH regions with the regulatory authorities and animal health industry participating as active observer members. The Office International des Epizooties (OIE) participates as associate member in the VICH process aiming at supporting and disseminating the outcomes at the worldwide level. The full title of VICH is the "International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products". VICH was officially launched in April 1996.
The number of Guidelines adopted by VICH since the start of the process requires now additional focus on maintenance and updating of the VICH Guidelines and a strategy for the second phase programme.

1 What is the scope of VICH?

The VICH is an international forum to provide guidance on technical requirements for the registration of new veterinary medicinal products in order to protect public health, animal health and welfare as well as the environment.
The scope of the VICH programme concerns veterinary medicinal products, including pharmaceuticals, biologicals and medicated premixes.
A number of factors influenced the establishment of VICH including:

- The need to establish and monitor internationally acceptable requirements that ensure high standards of public and animal health are maintained,
- The need to benefit from ICH[1] standards whenever possible and to use ICH experience in the development of VICH structure and processes,
- The growing focus within OIE member countries on the need for effective regulation of veterinary medicinal products,
- The need to co-ordinate regulatory response to emerging global issues impacting on regulation of veterinary medicinal products,
- The desire to reduce the use of test animals by eliminating the need for duplication of trials in each region,

[1] ICH – International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human use

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- The need for increased efficiency in the use of regulatory resources, while ensuring the effectiveness of the regulatory systems,
- The international drive to harmonize regulatory standards and minimize their impact on trade,
- The desire to minimize the cost of gaining registration and facilitate the number of innovative products entering the market in the VICH regions,
- The desire to minimize variability in registration requirements between VICH regions which can lead to uncertainty, duplication and inconsistency and add considerable delays to product entry into the market,
- The desire to minimize regulatory timetables which can delay availability of new and innovative medicines much needed by veterinarians and animal owners,
- The need to minimize variability of testing methods which can lead to difficulties in comparing data within and between the VICH regions.

VICH was established under the auspices of OIE to respond to these factors by developing harmonized requirements for registration. The VICH Strategy and VICH's work programme form the basis of that response.

2 What are the objectives of VICH?

- The objectives of VICH are to:

- Establish and monitor harmonized regulatory requirements for veterinary medicinal products in the VICH Regions, which meet high quality, safety and efficacy standards and minimize the use of test animals and costs of product development.
- Provide a basis for wider international harmonization of registration requirements.
- Monitor and maintain existing VICH guidelines, taking particular note of the ICH work program and, where necessary, update these VICH Guidelines.
- Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following the implementation of VICH guidelines.
- By means of a constructive dialogue between regulatory authorities and industry provide technical guidance enabling response to significant emerging global issues and science that impact on regulatory requirements within the VICH regions.

3 Guiding principles of VICH

- The general decision making process in VICH should remain that of consensus achieved by all parties.
- Procedures should ensure the smooth and consistent functioning of the process for preparation, consultation and adoption of guidelines.
- Acceptance of any new topics for harmonisation activities requires a thorough evaluation of the importance and feasibility of the project based on a detailed concept paper and acceptance of all full members. Particular consideration should be given to the adaptation of new ICH Guidelines.
- Recommendations on guidance should be based on scientific assessment of existing information. These guidelines should focus on the essential scientific requirements

needed to address a topic and should eliminate unnecessary or redundant requirements.

- Regular cost/benefit analyses of the VICH process should be performed and communicated.
- Once adopted, the VICH guidelines replace corresponding regional requirements.
- The VICH should be conducted in a transparent time- and cost-effective manner and should provide the opportunity for public comment on recommendations at the draft stage. An open and transparent consultation process should be maintained for revision of existing guidelines as well as any new draft guideline.
- All parties commit to provide the necessary human and material resources for the proper and timely functioning of groups and execution of agreed work. The experts should be chosen both on scientific merits and ability to work in a multicultural team environment as well as on skills in negotiation/finding compromises
- If an EWG cannot reach agreement, the SC should consider publishing the main outcomes in a status report document. In such cases a document should be prepared by the EWG including the points on which an agreement could not be reached.
- Applications for status as members/observers/interested parties should be encouraged, taking into account that continued efficiency in the operation of VICH should be preserved.

4 General Organisation

- The general organisation of VICH consists of a Steering Committee (SC) and Expert Working Groups (EWG).
- Basic responsibilities of the Steering Committee (SC) are described in the organisational charter.
- Basic responsibilities of the Expert Working Groups (EWG) are described in the organisational charter.
- Other responsibilities and activities of the SC and the EWGs are further developed in relevant guidance documents.

5 Communication

- The aim of VICH communication is to provide information to the public and interested organisations, and encourage opportunities for feedback on its work for all parties on:
    - VICH guidelines,
    - VICH process and procedures
    - Progress of active EWGs,
    - General information regarding VICH conferences etc…
- Communication and consultation with relevant organisations outside the committed regions should be optimised.

6 Decision-Making Process and Procedures

Prior to the launch of a new topic, the SC ensures that the following pre-requisites have been fulfilled, taking into account the existence of Regional Requirements:

- Identification of a need for harmonization ("Gap Analysis")
- Listing of existing legislation
- Anticipated benefit
- Impact Assessment
- Feasibility
- Expected timeframe
- Resources and costs needed
- Probability of success
- Resource need for industry and regulators following implementation of the requirements in new GLs

These requirements shall be considered when drafting a concept paper and are further detailed by the SC in the relevant guidance for preparing a concept paper (ref: VICH/97/037), including a specific timeline for completion.

Where the SC based on such an analysis decides to launch a new topic the work for developing a harmonised guideline is undertaken under the 9-step procedure agreed by VICH and as described in the Organisational Charter.